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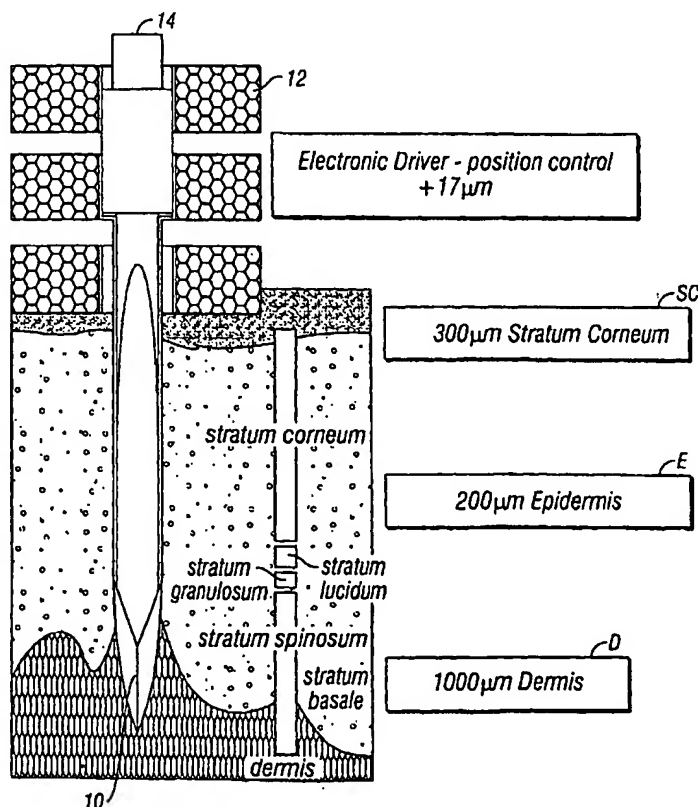
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[Continued on next page]

(54) Title: DEVICE AND METHOD FOR VARIABLE SPEED LANCET



(57) Abstract: A method of penetrating tissue is provided. The method comprises using a lancet driver to advance a lancet into the tissue; advancing the lancet at a first desired velocity in a second layer of tissue; and advancing the lancet at a third desired velocity in a third layer of tissue. In one embodiment, the method may include using a processor having logic for controlling velocity of the lancet in each layer of tissue. In another embodiment, the first velocity is at least partially determined based on hydration of the stratum corneum. It should also be understood that the lancet driver may be electromechanical.

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## DEVICE AND METHOD FOR VARIABLE SPEED LANCET

### BACKGROUND

Lancing devices are known in the medical health-care products industry for  
5 piercing the skin to produce blood for analysis. Typically, a drop of blood for analysis is  
obtained by launching or driving a lancet into tissue to create a small incision, which  
generates a small blood droplet on the tissue surface.

Current mechanical lancet launchers are configured to actuate ballistically. The  
lancet is driven out from the opening in the launcher and when a predetermined  
10 penetration depth is reached, a return spring propels the lancet back into the housing  
with roughly the same velocity as for the inbound. There is no mechanism to control the  
lancet in flight (inbound or outbound) other than a hard stop for maximum penetration.  
It is therefore impossible to control lancet velocity for skin properties, let alone skin  
anatomy differences, in these devices other than a crude depth setting. Known  
15 launchers may use stepped offsets in a range of 0.9 mm to 2.3 mm or switchable end  
caps to attempt to control lancet depth. The thicker the offset, the shallower the  
resulting penetration. These depth settings are, in actuality, a measurement of the  
protrusion of the lancet tip from the housing, and do not reflect the actual penetration  
depth of the lancet because of tenting or bending of skin before or during cutting.  
20 Unfortunately, without reliable lancet control during actuation, the pain and other  
drawbacks associated with using known mechanical lancet launchers discourage  
patients from following a structured glucose monitoring regime.

### SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks  
25 discussed above. Specifically, some embodiments of the present invention provide  
improved control of lancet or penetrating member velocity. At least some of these and  
other objectives described herein will be met by embodiments of the present invention.

In one aspect of the present invention, a method of penetrating tissue is  
provided. The method comprises using a lancet driver to advance a lancet into the

tissue; advancing the lancet at a first desired velocity in a first layer of tissue; advancing the lancet at a second desired velocity in a second layer of tissue; and advancing the lancet at a third desired velocity in a third layer of tissue. In one embodiment, the method may including using a processor having logic for controlling velocity of the lancet in each layer of tissue. In another embodiment, the first velocity is at least partially determined based on hydration of the stratum corneum. It should also be understood that the lancet driver may be electromechanical. The velocity may be determined based on cell population and distribution in the different zones of tissue. The processor may also determine what proportion of electrical power consumption is related to the stratum corneum by measuring differences between normal and hydrated stratum corneum.

In another embodiment according to the present invention, a method is provided for penetrating tissue. The method comprises using a drive force generator to advance a penetrating member along a penetration path into the tissue wherein the penetrating member having a penetrating member velocity equal to a first velocity in a first layer of tissue. Penetrating member velocity is determined at a plurality of locations along the penetration path. The method also includes adjusting penetrating member velocity at a plurality of locations along the penetration path prior to the penetrating member coming to a stop in the tissue. In another embodiment, the method may further include advancing the penetrating member at a maximum velocity through the stratum corneum, at a velocity in the epidermis sufficient to reduce shock waves to pain sensor in dermis, and at a velocity in the dermis is sufficient for efficient cutting of blood vessels without stimulating pain sensors.

In another aspect of the present invention, a lancing system is provided to drive a lancet during a lancing cycle and for use on a tissue site. The system comprises a lancet driver; a processor coupled to said lancet driver, the processor configured to adjust lancet velocity to achieve a desired velocity based on the layer of tissue through which the lancet is cutting. The system may include a user interface allowing a user to adjust penetration depth based on stratum corneum hydration. The user interface may also allow a user to adjust lancet velocity based on user pain. The system may also include memory for storing at least one of the following to determine a skin profile:

energy consumed per lancing event; time of day. In a still further aspect of the present invention, a further method of driving a lancet into a tissue site is provided. The method comprises calculating stratum corneum thickness based on energy consumed and depth of lancet penetration on a previous lancing cycle; driving the lancet into the tissue site, wherein the lancet does not penetrate more than a desired distance beyond the stratum corneum thickness, the stratum corneum thickness determined by an inflection point of energy consumption when the lancet exits that layer. In one embodiment, the processor controls penetrating member velocity and there are at least a number different decision points to change penetrating member velocity during penetration, said number selected from: 5, 10, 15, 20, 30, 40, or 50.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

#### Brief description of the drawings

Figure 1 is a diagram shows a lancet penetrating layers of the skin in a histological section.

Figure 2 is a skin anatomy drawing showing the various skin layers with distinct cell types.

Figure 3 shows lancet trajectories plotted in terms of velocity and position. Line (a) indicates the lancet position, line (b) indicates the skin position as it interacts with the lancet. Line (c) indicates the actual penetration depth of the lancet within the skin.

Figure 4 is a diagram showing variation of lancet velocity through different phases of the inbound trajectory.

Figure 5 shows one embodiment of an invention according to the present invention for use with a multiple lancet cartridge.

Figure 6 is a graph showing a difference in power depending on the level of stratum corneum hydration.

DESCRIPTION

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It should be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

The pain and sufficiency of blood yield of a capillary blood sample from the skin may vary based in part on the efficiency of the cutting device within skin layers. Specifically, the ability to control the lancet trajectory in terms of the velocity profile within the spatial constraints of the skin layers will determine, at least in part, how painless, and how efficient the cutting is.

There is a regional variation in cell type from the surface of the skin down through the epidermis and dermis. As a non-limiting example, cutting the blood vessels yields blood volumes of about 1 - 3  $\mu$ L using lancets of diameters 300 to 400  $\mu$ m at depths of about 0.1- 1.5 mm. It is desirable, in one embodiment, to only penetrate deep enough to reach and cut the required amount of blood vessels for a blood sample.

Penetrating too deep causes more pain than necessary, penetrating too shallow does

not yield enough blood or no blood. In one embodiment, cutting the capillaries in the superficial reticular layer of the dermis with a 300  $\mu\text{m}$  diameter lancet is sufficient to yield enough blood to fill current state of the art glucose test strips using 0.3 – 0.5  $\mu\text{L}$  of blood.

5           In one ideal situation, a painless incision by the lancet would cut enough blood vessels to yield a spontaneous blood sample, which would reach the surface of the tissue for analyte testing for such metabolites as glucose without cutting many nerves or disturbing the elastin fiber net, collagen fibers. Efficient cutting would be defined as controlled lancing for minimal pain to yield a required blood volume for testing at a  
10 shallow depth which equates to cutting the capillary mesh in the superficial reticular layer.

          Using an electronically driven lancet, (where position and velocity are accurately controlled) the user can fine-tune the cutting process depending on the cell population and distribution in the different layers, for example, based on whether nerves are  
15 present or not, or based on the elastin or collagen fiber content orientation or distribution.

          Accurate depth control relates to generating a spontaneous blood sample with minimum pain. It is desirable, in one embodiment, to vary the velocity of the cutting lancet based on the cell population. The surface of the skin is comprised of dead or  
20 dying cells (the stratum corneum). It is a horny layer, which may vary from 100  $\mu\text{m}$  to 600  $\mu\text{m}$  in thickness, and represents the top layer of the epidermis. The deeper layers of the epidermis can be grouped into 5 different layers, the last of which separates it from the dermis. The epidermis has little innervation compared to the dermis. The distance from the bottom of the stratum corneum to the capillary loops of the dermal  
25 papillae is about 300  $\mu\text{m}$ . In one embodiment, using an electric lancet actuator coupled with a position transducer, it is possible to resolve position of the lancet within the skin to an accuracy of  $\pm 17 \mu\text{m}$ . This translates in to over 40 steps through which the velocity can be fed back and controlled. It should be understood, of course, that sensors of other accuracies, as known in the art, may also be used. Embodiments of  
30 the invention include devices and methods to control the velocity of the lancet within the different anatomical layers of the skin to achieve the most efficient cutting. Advantages



are achieved by use of a miniaturized electronic lancing system for efficiently cutting through the layers of skin by optimizing the velocity profile and using position control feedback mechanism is described.

Referring now to Figure 1, layers of the skin are shown in this histological section. Skin is composed of various distinct anatomical regions (Figure 1). The main function of the epidermis E is to protect the body from harmful influences from the environment and against fluid loss. The dermis D is the thick layer of connective tissue to which the epidermis D is attached.

The epidermis E is composed of an outermost layer is the stratum corneum, which mainly consists of dead keratinized cells. Variations in the thickness of the epidermis (~0.1 mm. in thin skin, 1 mm or more in thick skin) are mainly the result of variations in the thickness of the stratum corneum (SC). The epidermis E composed of stratum lucidum (consisting of several layers of flattened dead cells), stratum granulosum (consisting of a few layers of flattened cells) stratum spinosum (cells are irregularly polygonal and often separated by narrow, translucent clefts), and stratum basale. Stratum basale is the deepest layer or zone of the epidermis and separates the epidermis from the dermis. It consists of a single layer of columnar or cuboidal cells, which rest on the basement membrane. Basal cells are the stem cells of the epidermis.

The dermis D is where capillaries and blood vessels are located and nerves supported by connective tissue including collagen fibers and elastin are found. The collagen fibers give the dermis its strength, the elastin and microfibrils give skin its elasticity. Its deepest part continues into the subcutaneous tissue without a sharply defined boundary making thickness difficult to determine. It is about 1-2 mm for "average" skin.

For a blood sample to reach the surface of the tissue or skin following lancing, several factors come in to play. The lancet may cut through each layer, it may reach the required depth to cut a sufficient number of blood vessels for the desired blood volume, and then the blood may be able to flow up the wound tract created by the lancet and arrive at the surface of the skin. If blood arrives at the surface of the finger without "milking" of the finger, this is called a 'spontaneous' blood sample. Generating a

spontaneous blood sample is crucial when interfacing a measurement unit (e.g. test strip) to the lancing event. The lancet penetration may be deep enough that adequate vessels are cut to release the blood, and not too deep that unnecessary pain is generated. Thus accurate depth control is the primary factor controlling a spontaneous blood sample.

Maintaining wound patency is also a factor for achieving a "successful" bleeding event. Many times blood is prevented from flowing upstream the wound channel due to closure of the channel by retraction forces of surrounding elastic fibers, which cause the wound channel to close before the blood can surface. Keeping the wound open and allowing spontaneous blood flow can be achieved by slowly retracting the lancet up the wound channel.

As seen in Figure 1, the thickness of the stratum corneum SC, epidermis E and dermis D are given for comparison. In one embodiment, the lancet or penetrating member 10 driven along a penetration path by an electronic driver 12, may reach the blood vessels located in the dermis D, and cut enough of them to produce a sample of blood for testing. In one embodiment, the cutting process may be as painless as possible. This may be achieved by a rapid cutting speed and accurate control of depth of penetration.

The ability to control the lancet or penetrating member trajectory in terms of the velocity profile of the lancet or penetrating member 10 within the spatial constraints of the skin layers may result in less painful, more efficient cutting of the skin. In one embodiment, the user can fine tune the cutting process depending on the skin layer and cell population of the different zones using an electronically driven lancet 10, where position and velocity are accurately controlled i.e. whether nerves are present or not as seen in Figure 2. Specifically, Figure 2 shows skin anatomy relevant to capillary blood sampling. The skin layers are comprised of distinct cell types. Variation of lancet velocity based on cell populations in the different layers allows for very precise cutting.

For an electronic or electromechanical lancet driver 12, such as the controllable electronic drivers described in copending U.S. Patent Application titled "Tissue Penetration Device" (Attorney Docket No. 38187-2551), operating at a lancing velocity

in the range of about 4 - 10 m/s is possible. This is two to four times faster than the commonly available mechanically actuated devices, (which operate in the range of 1 - 2 m/s). Ballistic mechanical launcher devices are also not equipped with position feedback mechanisms. Depth control in these devices is usually by an end cap with stepped offsets. The lancet barrel hitting the back of the cap controls the lancet depth. The thicker the offset, the shallower the resulting penetration. Users select the depth they prefer by dialing in the number represented on the device. In one embodiment, penetration settings vary from about 0.5 - 2.0 mm with steps of about 0.2 mm to 0.4 mm. The accuracy of the depth variation is of the order of  $\pm 0.1$  mm with the selected puncture depth.

As a nonlimiting example, using an electric lancet driver 12 coupled to an optical position sensor 14, velocity of the lancet 10 may be controlled at any stage during the actuation and retraction. In one embodiment, the accuracy of the device in terms of position may be different for the inbound and outbound phase of the movement. Two different types of sensor readings may be applied for the inbound and the outbound. The current embodiment achieves 70  $\mu\text{m}$  accuracy on the inbound phase using a so called "single (falling) edge detection" and 17  $\mu\text{m}$  for the outbound, using a so called "four (rising and falling) edge detection". In this nonlimiting example, the accuracy of the velocity control is within 1% at a speed of 5 m/s.

Referring now to Figure 3 for another nonlimiting example, lancet position and velocity during an actuation and retraction event is shown. Lancet trajectories in Figure 3 are plotted in terms of velocity and position. Line (a) indicates the lancet position, line (b) indicates the skin position as it interacts with the lancet. Line (c) indicates the actual penetration depth of the lancet within the skin. The difference between the elastic tenting or bending of the skin and the lancet position is the actual depth of penetration. Skin tenting can account for up to 100  $\mu\text{m}$ . Inelastic tenting (the fact that the skin does not return to its original position post lancet removal) is on average about 100  $\mu\text{m}$ . The invention focuses on controlling the lancet velocity while on the inbound trajectory in the finger skin.

As seen in Figure 3, the lancet 10 in one embodiment undergoes an acceleration phase 50 to a specified velocity from where it coasts until it contacts the skin. This

velocity may be preset. At this point any type of velocity profile can be defined until it reaches the target depth. There is a braking period 52 included which allows the lancet 10 to come to a complete stop at the selected penetration depth for this embodiment. The lancet 10 is then retracted from the tissue or finger, and returns to the housing.

5 Referring now to Figure 4, the area of interest is the velocity profile 100 while the lancet is cutting through the skin layers in the finger until it reaches a predetermined depth. More specifically, variation of lancet velocity through different phases of the inbound trajectory is shown in Figure 4. In this embodiment, Phase I corresponds to the stratum corneum, phase II to the epidermis and phase III to the dermis. At each phase  
10 (and during the phase), the options are to maintain current velocity, increase current velocity or decrease current velocity. Based on the thickness of the stratum corneum, velocity could be monitored and changed in this embodiment at 9 points in the stratum corneum, 6 points in the epidermis, and 29 points in the dermis using the four edge detection algorithm and the 360 strips per inch encoder strip. It should be noted that  
15 although the embodiment of the driver discussed herein produces the previously discussed number of monitoring points for a given displacement, other driver and position sensor embodiments may be used that would give higher or lower resolution.

For the purposes of the present discussion for this nonlimiting example, the skin is viewed as having three distinct regions or tissue layers: the stratum corneum SC  
20 (Phase I), the epidermis E (Phase II) and the dermis D (Phase III). In one embodiment, the lancet 10 is accelerated to a first desired velocity. This velocity may be predetermined or it may be calculated by the processor during actuation. The processor is also used to control the lancet velocity in tissue. At this velocity, the lancet 10 will impact the skin and initiate cutting through the stratum corneum. The stratum  
25 corneum is hard, hence in this embodiment, maximum velocity of the lancet 10 may be employed to efficiently cut through this layer, and this velocity may be maintained constant until the lancet passes through the layer. Power will likely need to be applied to the lancet drive 12 while the lancet is cutting through the stratum corneum in order to maintain the first velocity. Average stratum corneum thickness is about 225  $\mu\text{m}$ . Using  
30 a four-edge detection algorithm for the position sensor 14 of this embodiment, the opportunity to verify and feed back velocity information can be carried out at 225/17 or

roughly 13 points. In another embodiment accelerating through the stratum corneum following impact may improve cutting efficiency. Acceleration may be possible if the lancet has not reached its target or desired velocity before impact. Figure 4 shows the result of increasing ((a) arrows, maintaining ((b) arrows) or reducing ((c) arrows) velocity on the lancet trajectory for each of the tissue layers.

On reaching the epidermis E (Phase II), an embodiment of a method may decrease the velocity ((c) arrows) from the first velocity so that tissue compression is reduced in this second tissue layer. Thus the lancet 10, in this nonlimiting example, may have a second desired velocity that is less than the first velocity. The reduced speed in the second tissue layer may reduce the pain experienced by the mechanoreceptor nerve cells in the dermal layer (third tissue layer). In the absence of tissue compression effects on the dermal layer, however, lancet velocity may be kept constant for efficient cutting (i.e. second velocity may be maintained the same as the first velocity). In another embodiment, velocity may be increased in the second tissue layer from the first velocity.

In Phase III, the lancet or penetrating member 10 may reach the blood vessels and cut them to yield blood. The innervation of this third tissue layer and hence pain perception during lancing could be easily affected by the velocity profile chosen. In one embodiment, a third desired velocity may be chosen. The velocity may be chosen to minimize nerve stimulation while maintaining cutting efficiency. One embodiment would involve reducing velocity from the second velocity to minimize pain, and may increase it just before the blood vessels to be cut. The number of velocity measurement steps possible for the position sensor described above in the dermis is approximately 58. The user would determine the best velocity/cutting profile by usage. The profile with the least amount of pain on lancing, yielding a successful blood sample would be programmable into the device.

Currently users optimize depth settings on mechanical launchers by testing various settings and through usage, settle on a desired setting based on lancing comfort. Embodiments of the device and methods discussed herein provide a variety of velocity profiles (Figure 4), which can be optimized by the user for controlled lancing, and may include: controlling the cutting speed of a lancet with the lancet within the skin;

adjusting the velocity profile of the lancet while the lancet is in the skin based upon the composition of the skin layers; lancing according to precise regional velocity profiles based on variation in cell type from the surface of the skin down through the epidermis and dermis; lancing at a desired velocity through any tissue layer and varying the  
5 velocity for each layer. This may include maximum velocity through the stratum corneum, mediation of velocity through epidermis to minimize shock waves to pain sensors in dermis, and mediation of velocity through dermis for efficient cutting of blood vessels without stimulating pain receptors.

Referring now to Figure 5, a processor 120 according to the present invention is  
10 used to control the lancet driver 122. As previously discussed, a suitable lancet driver may be found in commonly assigned, copending U.S. Patent application titled "Tissue Penetration Device", U.S. Ser. No.: 10/127,395 (Attorney docket number 38187-2551) filed on April 19, 2002. The lancet or penetrating member driver may be adapted for use with a cartridge 124 holding a plurality of lancets or penetrating members 126 which  
15 may be actuated to extend outward as indicated by arrow 128. A suitable cartridge may be found in commonly assigned, copending U.S. Patent Application Ser. No. 10/324,053 (Attorney docket number 38187-2609) filed on December 18, 2002. The system may also include memory 130 for storing at least one of the following to determine a skin profile: energy consumed per lancing event; stratum corneum  
20 hydration; time of day of stratum corneum hydration measurement.

Referring now to Figure 6, the amount of power used to penetrate into the tissue may increase with increased hydration of the stratum corneum. The present invention provides methods for compensating for variation in stratum corneum hydration. Hydration has its strongest effect in the outer layer of the stratum corneum. Studies  
25 have shown that coenocytes can swell up to 80% larger on hydration. It is useful to determine what proportion of electrical power consumption is related the change in thickness of stratum corneum from measuring electrical property differences between normal and hydrated stratum corneum. The present invention determines the amount of energy used to achieve a certain penetration depth at various states of stratum  
30 corneum hydration. By recording a history of penetration energy and the hydration level, the amount of extra energy used during lancing may be attributed to the change in

thickness of the stratum corneum brought about by increased or decreased hydration. In one embodiment, the user will adjust penetration depth, lancing velocity, lancing velocity for certain tissue layers, time of day, or to account for in stratum corneum variations due to hydration level.

5           The pain and efficiency of blood yield of a capillary blood sample from the skin may very well depend on the efficiency of the cutting device within skin layers. The ability to control the lancet trajectory in terms of the velocity profile within the skin layers will determine how painless, and how efficient the cutting is. Using an electronically driven lancet, where position and velocity are accurately controlled the user can fine-  
10       tune the cutting process depending on the cell population and distribution in the different zones for efficient, painless and reproducible lancing.

          While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures  
15       and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. Some other advantages of the disclosed embodiments and features of  
20       additional embodiments include: a high number of penetrating members such as 25, 50, 75, 100, 500, or more penetrating members may be put on a disk or cartridge; molded body about a lancet may be used but is not a necessity; manufacturing of multiple penetrating member devices is simplified through the use of cartridges; handling is possible of bare rods metal wires, without any additional structural features, to actuate them into tissue; maintaining extreme (better than 50 micron -lateral- and better than 20  
25       micron vertical) precision in guiding; and storage system for new and used penetrating members, with individual cavities/slots is provided. Any of the dependent claims which follow may be combined with any independent claim which follows.

          Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the  
30       invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

## WHAT IS CLAIMED IS:

- 1           1.     A system configured to drive a penetrating member, the system  
2 comprising:  
3                 a penetrating member driver;  
4                 a processor controlling said driver and configured to adjust penetrating  
5 member velocity.
- 1           2.     A method of penetrating tissue comprising:  
2                 using a lancet driver to advance a lancet into said tissue;  
3                 advancing said lancet at a first desired velocity in a first layer of tissue;  
4                 advancing said lancet at a second desired velocity in a second layer of  
5 tissue; and  
6                 advancing said lancet at a third desired velocity in a third layer of tissue.
- 1           3.     The method of claim 2 further comprising using a processor having logic  
2 for controlling velocity of the lancet in each layer of tissue.
- 1           4.     The method of claim 2 wherein said lancet achieves a lancet velocity  
2 between about 4 to 10 m/s while in at least one of the layers of tissue.
- 1           5.     The method of claim 2 wherein said lancet achieves a penetration depth,  
2 as measured from a surface of the tissue, of between about 0.5 to about 2.0 mm.
- 1           6.     The method of claim 2 wherein said second desired velocity is sufficient to  
2 minimize nerve stimulation while maintaining cutting efficiency.
- 1           7.     The method of claim 2 wherein said second velocity is the same as the  
2 first velocity.
- 1           8.     The method of claim 2 wherein said first velocity is at least partially  
2 determined based on hydration of the stratum corneum.
- 1           9.     The method of claim 2 wherein said second velocity is at least partially  
2 determined based on hydration of the stratum corneum.



- 1           10.    The method of claim 2 further comprising determining hydration of the  
2   stratum corneum.
- 1           11.    The method of claim 2 wherein said lancet driver is electromechanical.
- 1           12.    The method of claim 2 wherein said lancet driver is coupled to position  
2   sensor for determining lancet position during lancet actuation.
- 1           13.    The method of claim 2 further comprising adjusting lancet penetration  
2   depth based on stratum corneum hydration.
- 1           14.    The method of claim 2 wherein a four edge algorithm is used to control  
2   lancet velocity.
- 1           15.    The method of claim 2 wherein there are at least 30 different decision  
2   points to change lancet velocity during penetration.
- 1           16.    The method of claim 2 wherein there are at least 30 different decision  
2   points to change lancet velocity prior to the lancet reaching a stopped position in the  
3   tissue.
- 1           17.    The method of claim 2 further comprising a position sensor to resolve  
2   position of the lancet within the skin to an accuracy of about  $\pm 17$  microns.
- 1           18.    The method of claim 2 further comprising a position sensor having a 360  
2   strip per inch encoder strip.
- 1           19.    The method of claim 2 further comprising using a first detection algorithm  
2   on a lancet inbound phase and a second detection algorithm on a lancet outbound  
3   phase.
- 1           20.    The method of claim 2 controlling lancet velocity to within 1 % at a speed  
2   of 5 m/s.
- 1           21.    The method of claim 2 lancing according to regional velocity profiles  
2   based on variation of cell type.
- 1           22.    The method of claim 2 lancing according to regional velocity, said velocity  
2   base on changes of regional cell types and the resistance they provide.

1           23.    The method of claim 2 lancing according to regional velocity profiles  
2    based on location to pain sensors.

1           24.    The method of claim 2 wherein position and velocity are determined based  
2    on cell population and distribution in the different zones of tissue.

1           25.    The method of claim 2 wherein the processor measures differences  
2    between normal and hydrated stratum corneum and determines what proportion of  
3    electrical power consumption is related to the increase in stratum corneum thickness.

1           26.    The method of claim 2 wherein said lancet has a maximum velocity  
2    through a stratum corneum, has a velocity in the epidermis sufficient to reduce shock  
3    waves to pain sensor in dermis, and a velocity through in the dermis sufficient for  
4    efficient cutting of blood vessels without stimulating pain sensors.

1           27.    A method of penetrating tissue having a plurality of layers, the method  
2    comprising:  
3                using a drive force generator to advance a penetrating member along a  
4    penetration path into said tissue, said penetrating member having a penetrating  
5    member velocity equal to a first velocity in a first layer of tissue;  
6                determining penetrating member velocity at a plurality of locations along  
7    said penetration path; and  
8                adjusting penetrating member velocity at a plurality of locations along said  
9    penetration path prior to the penetrating member coming to a stop in said tissue.

1           28.    A method of penetrating tissue having a plurality of layers, the method  
2    comprising:  
3                using a lancet driver to advance a lancet into said tissue, said lancet  
4    having a lancet velocity equal to a first velocity in a first layer of tissue;  
5                adjusting lancet velocity to achieve a desired velocity based on the layer  
6    of tissue through which the lancet is cutting.

1           29.    The method of claim 28 further comprising:  
2                adjusting the lancet velocity to achieve a second velocity in a second  
3    tissue layer, said adjusting based upon characteristics of the second tissue layer and  
4    said adjusting selected from one of the following: increasing velocity from said first

5 velocity, decreasing velocity from said first velocity, or maintaining a velocity equal to  
6 said first velocity;  
7 adjusting the lancet velocity to achieve a third velocity in a third tissue  
8 layer, said adjusting based upon characteristics of the third tissue layer and said  
9 adjusting selected from one of the following: increasing velocity from said second  
10 velocity, decreasing velocity from said second velocity, or maintaining a velocity equal  
11 to said second velocity.

1 30. A method of penetrating tissue comprising:  
2 using a lancet driver to advance a lancet into said tissue;  
3 adjusting the lancet velocity based on stratum corneum hydration.

1 31. The method of claim 30 further comprising characterizing tissue using an  
2 OCT device.

1 32. The method of claim 30 further comprising adjusting velocity to account for  
2 up to 150 micron thickness change in stratum corneum when hydrated.

1 33. A lancing system configured to drive a penetrating member during a  
2 lancing cycle and used on a tissue site, the system comprising:  
3 a penetrating member driver;  
4 a processor coupled to said driver, said processor configured to adjust  
5 lancet velocity to achieve a desired velocity based on the layer of tissue through which  
6 the lancet is cutting.

1 34. The system of claim 33 further comprising a user interface on said driver  
2 allowing a user to adjust penetration depth based on stratum corneum hydration.

1 35. The system of claim 33 further comprising a user interface on said driver  
2 allowing a user to adjust lancet velocity based on user pain.

1 36. The system of claim 33 further comprising memory for storing at least one  
2 of the following to determine a skin profile: energy consumed per lancing event; time of  
3 day.

1 37. The system of claim 33 wherein:

2           said processor has logic for using said driver to advance a lancet into said  
3 tissue, said penetrating member having a penetrating member velocity equal to a first  
4 velocity in a first layer of tissue;

5           said processor has logic for adjusting penetrating member velocity in the  
6 skin to achieve a desired velocity based on the layer of tissue through which the  
7 penetrating member is cutting.

1           38.   The system of claim 33 wherein said driver accelerates said penetrating  
2 member to achieve a penetrating member velocity between about 4 to 10 m/s while in at  
3 least one of the layers of tissue.

1           39.   The system of claim 33 wherein said driver advances said penetrating  
2 member to achieve a penetration depth, as measured from a surface of the tissue, of  
3 between about 0.1 to about 2.0 mm.

1           40.   The system of claim 33 wherein velocity of said penetrating member is  
2 sufficient to minimize nerve stimulation while maintaining cutting efficiency.

1           41.   The system of claim 33 wherein said driver accelerates said penetrating  
2 member so that velocity in through a second layer of tissue is the same as velocity  
3 through a first layer.

1           42.   The system of claim 33 wherein said driver advances said penetrating  
2 member at a first velocity at least partially determined based on hydration of the stratum  
3 corneum.

1           43.   The system of claim 33 wherein said driver advances said penetrating  
2 member at a second velocity at least partially determined based on hydration of the  
3 stratum corneum.

1           44.   The system of claim 33 wherein said processor determines hydration of  
2 the stratum corneum based in part on energy consumed during a lancing event.

1           45.   The system of claim 33 wherein said processor determines hydration of  
2 the stratum corneum based in part on energy consumed during a previous lancing  
3 event.

1        46.    The system of claim 33 wherein said penetrating member driver is  
2    electromechanical.

1        47.    The system of claim 33 wherein said penetrating member driver includes a  
2    position sensor for determining penetrating member position during penetrating member  
3    actuation.

1        48.    The system of claim 33 wherein said processor adjusts penetrating  
2    member penetration depth based electrical parameters to compensate for stratum  
3    corneum hydration.

1        49.    The system of claim 33 wherein said processor uses a four edge algorithm  
2    is used to control penetrating member velocity.

1        50.    The system of claim 33 wherein said processor controls penetrating  
2    member velocity and there are at least a number different decision points to change  
3    penetrating member velocity during penetration, said number selected from: 5, 10, 15,  
4    20, 30, 40, or 50.

1        51.    The system of claim 33 wherein said processor controls penetrating  
2    member velocity and there are at least a number different decision points to change  
3    penetrating member velocity during penetration prior to reaching a maximum  
4    penetration depth, said number selected from: 5, 10, 15, 20, 30, 40, or 50.

1        52.    The system of claim 33 further comprising a position sensor to resolve  
2    position of the penetrating member within the skin to an accuracy selected from: about  $\pm$   
3    20 microns, about  $\pm$  17 microns, about  $\pm$  15 microns, about  $\pm$  12 microns, about  $\pm$  10  
4    microns or less.

1        53.    The system of claim 33 further comprising a position sensor having a 360  
2    strip per inch encoder strip.

1        54.    The system of claim 33 wherein said processor uses a first detection  
2    algorithm on a penetrating member inbound phase and a second detection algorithm on  
3    a penetrating member outbound phase.

1        55.    The system of claim 33 wherein said processor controls penetrating  
2 member velocity to within 1 % at a speed of 5 m/s.

1        56.    The system of claim 33 wherein said processor controls lancing according  
2 to regional velocity profiles based on variation of cell type.

1        57.    The system of claim 33 wherein said processor controls lancing according  
2 to regional velocity, said velocity based on changes of regional cell types and the  
3 resistance they provide.

1        58.    The system of claim 33 wherein said processor controls lancing according  
2 to regional velocity profiles based on location of pain sensors.

1        59.    The system of claim 33 wherein said processor controls position and  
2 velocity based at least in part on cell population and distribution in the different zones of  
3 tissue.

1        60.    The system of claim 33 wherein the processor adjusts penetrating  
2 member penetration depth based electrical parameters to compensate for stratum  
3 corneum hydration.

1        61.    The system of claim 33 wherein said driver advances said penetrating  
2 member has a maximum velocity through a stratum corneum, has a velocity in the  
3 epidermis sufficient to reduce shock waves to pain sensor in dermis, and a velocity  
4 through in the dermis sufficient for efficient cutting of blood vessels without stimulating  
5 pain sensors.

1        62.    A lancing system configured to drive a lancet during a lancing cycle and  
2 used on a tissue site, the system comprising:  
3            a drive force generator coupled to an energy sensor sufficient for  
4 measuring energy used to drive said lancet into the tissue site;  
5            a processor on said lancet driver, said processor calculating lancet  
6 velocity and sending signals to said drive force generator to adjust lancet velocity based  
7 at least in part on characteristics of tissue being cut by the lancet

1        63.    The system of claim 62 further comprising memory for storing advancing  
2 said lancet at a first desired velocity in a first layer of tissue;

3           advancing said lancet at a second desired velocity in a second layer of  
4 tissue; and  
5           advancing said lancet at a third desired velocity in a third layer of tissue.

1           64.   A lancing system configured to drive a lancet during a lancing cycle and  
2 used on a tissue site, the system comprising:  
3           a drive force generator;  
4           a controller with logic for controlling the drive force generator to advance a  
5 penetrating member along a penetration path into said tissue, said penetrating member  
6 having a penetrating member velocity equal to a first velocity in a first layer of tissue;  
7           wherein said controller has logic for determining penetrating member  
8 velocity at a plurality of locations along said penetration path; and  
9           wherein said controller has logic for adjusting penetrating member velocity  
10 at a plurality of locations along said penetration path prior to the penetrating member  
11 coming to a stop in said tissue.

1           65.   A method of driving a lancet into a tissue site, said method comprising:  
2           calculating stratum corneum thickness based on energy consumed and  
3 depth of lancet penetration on a previous lancing cycle;  
4           driving the lancet into the tissue site, wherein the lancet does not  
5 penetrate more than a desired beyond the stratum corneum thickness, said stratum  
6 corneum thickness determined by an inflection point of energy consumption when the  
7 lancet exits that layer.

1           66.   The method of claim 65 further comprising:  
2           stopping said lancet at a desired depth without multiple oscillations against  
3 tissue in the tissue site, wherein said desired depth is less than a sum of the stratum  
4 corneum thickness and a predetermined depth from the stratum corneum.

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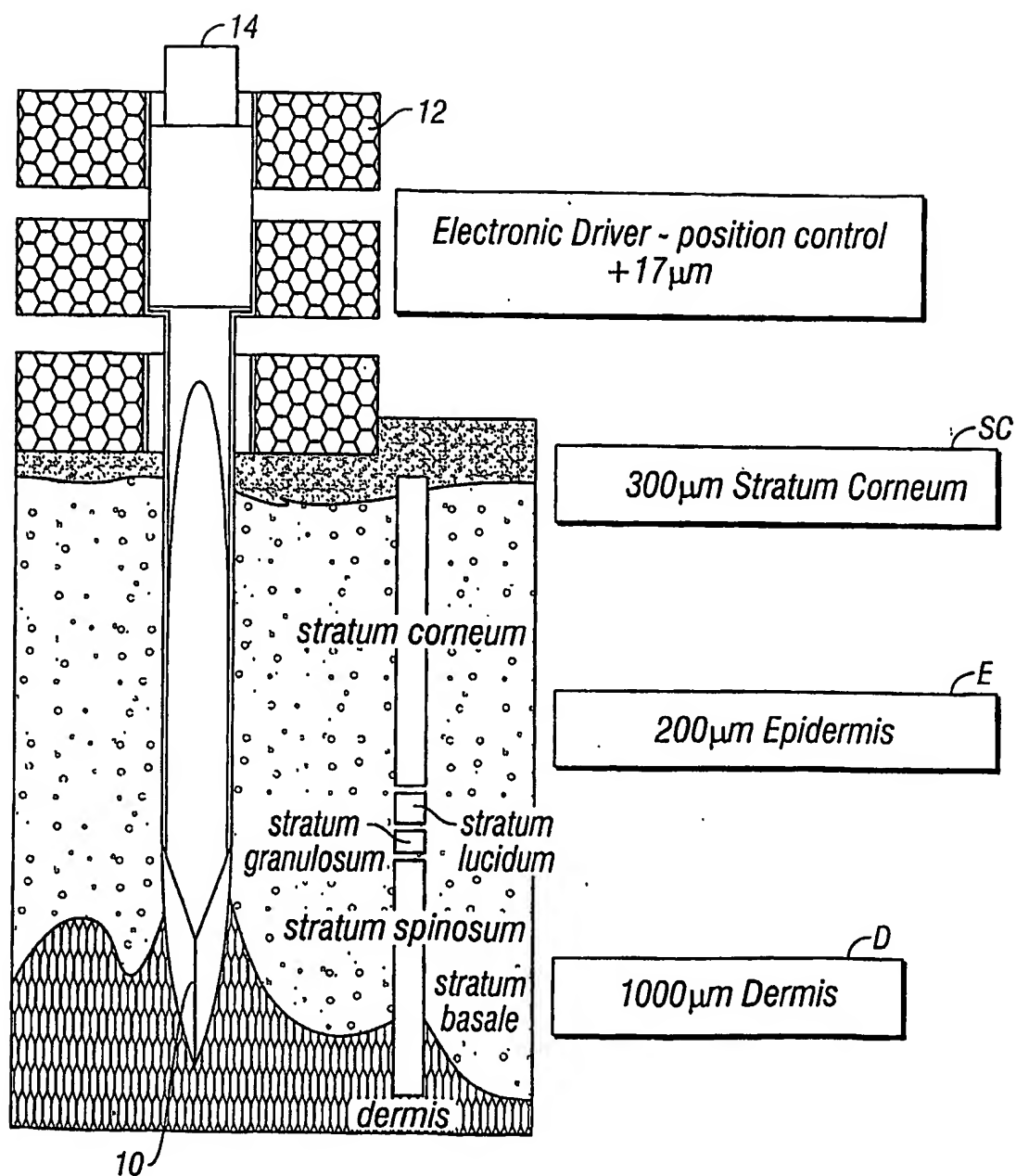


FIG. 1



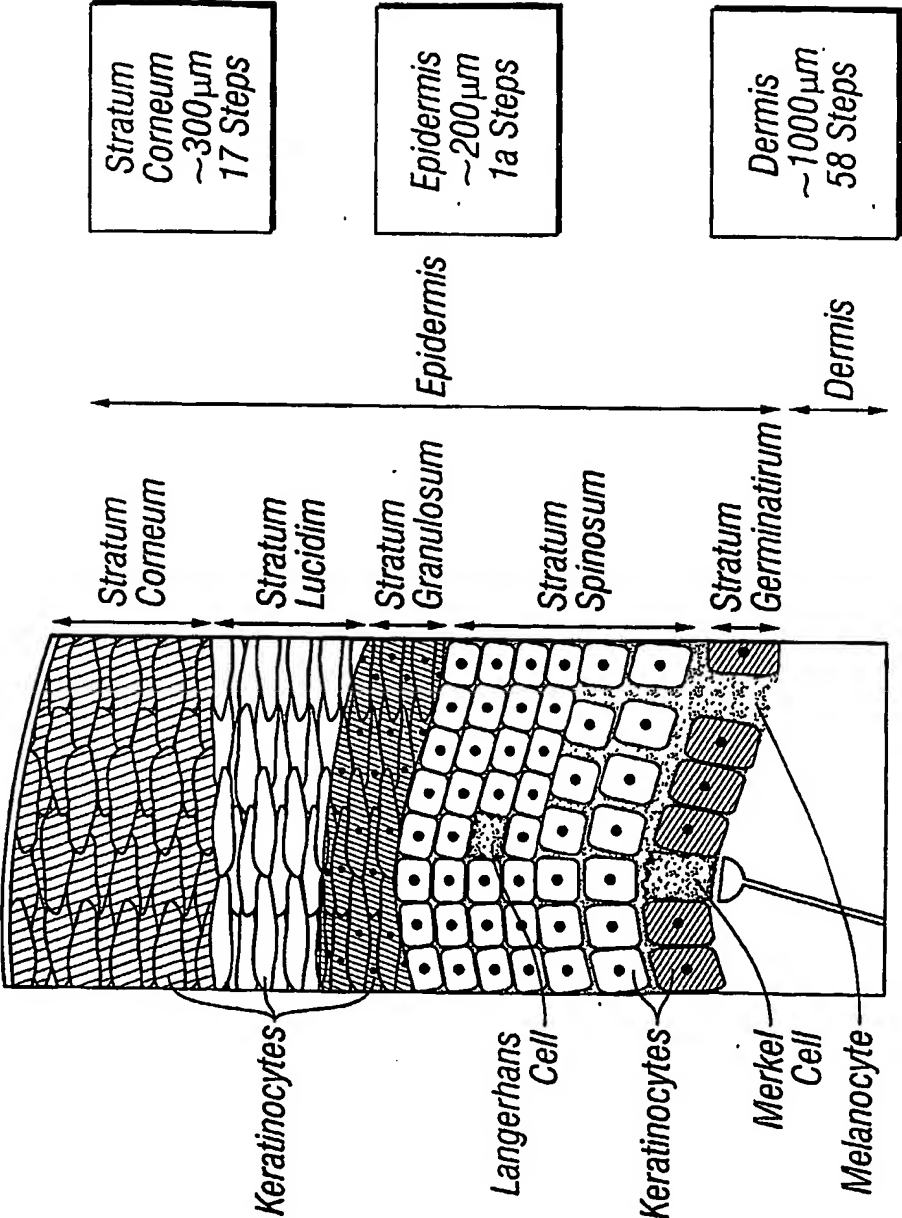


FIG. 2

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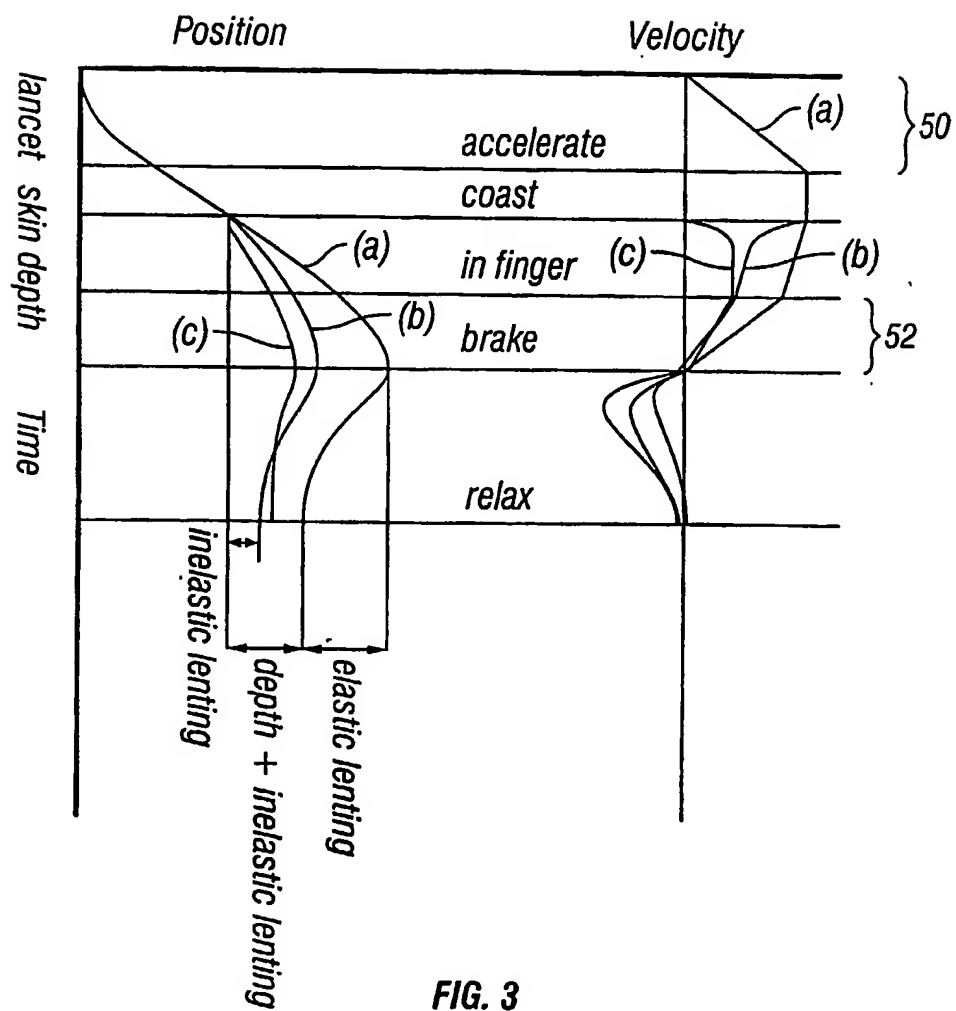


FIG. 3

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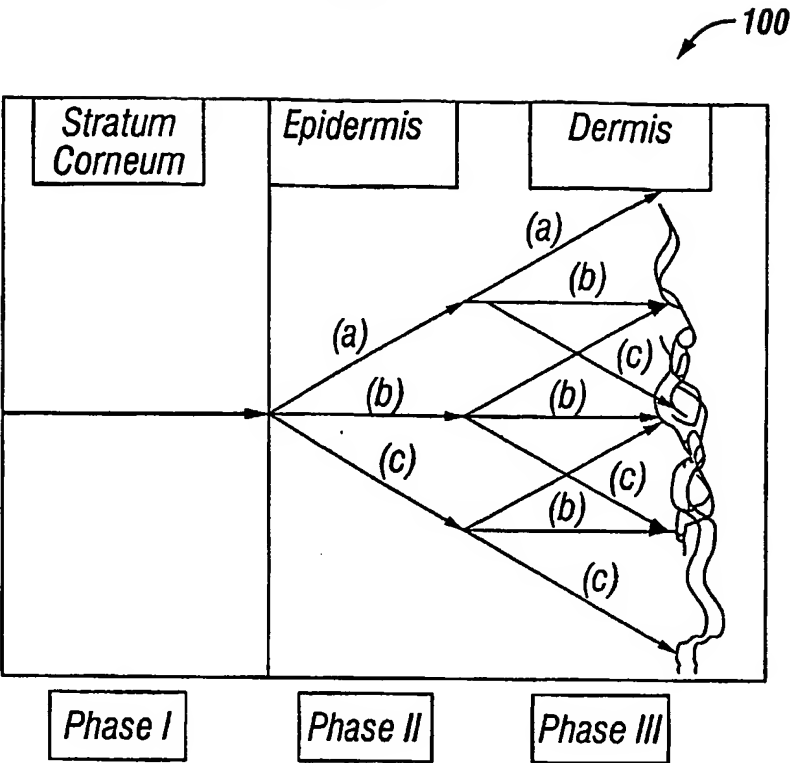


FIG. 4

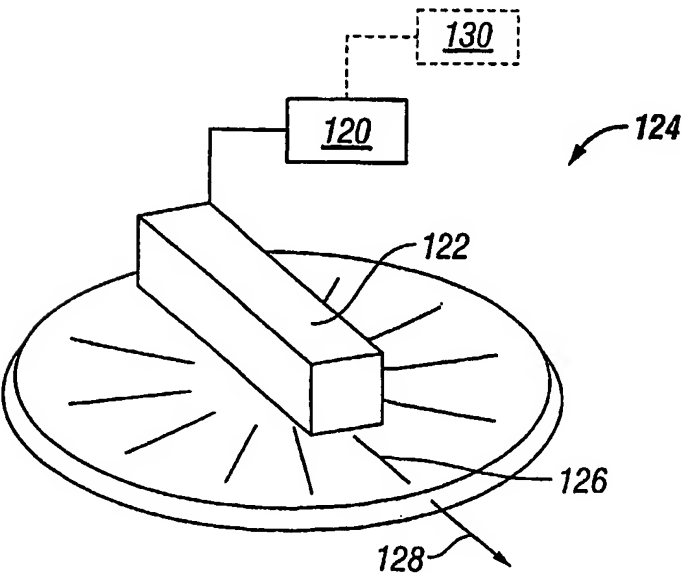


FIG. 5

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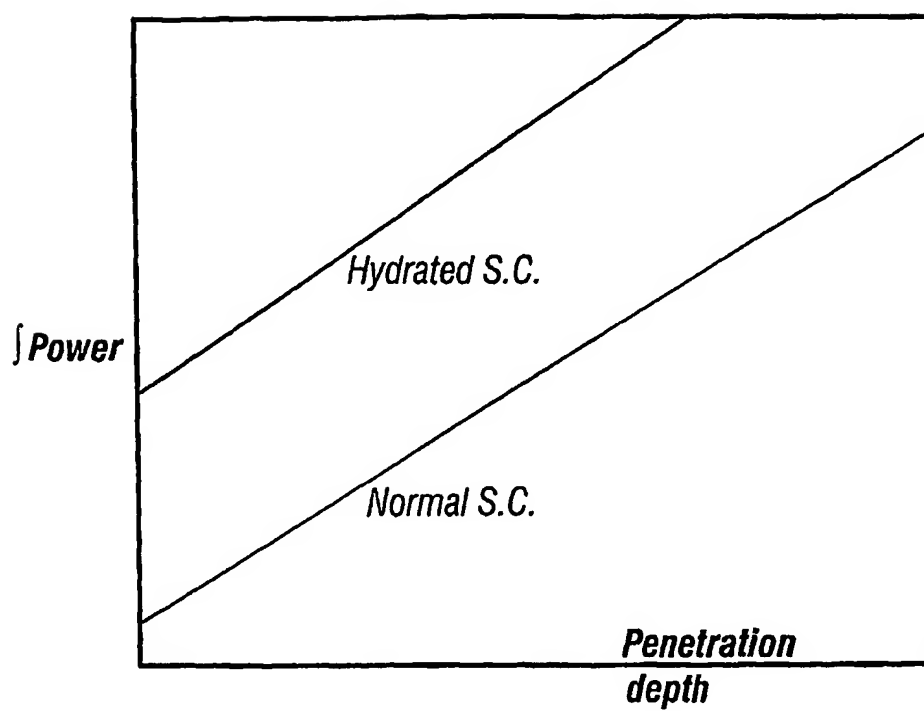


FIG. 6